DETAILED ACTION

1. Applicant's response to the last Office Action, filed 3/27/2008, has been entered and made of record.

Applicant has amended claims 4, 12. Claims 13 have been added. Claims 1-13 are currently pending.

Applicants arguments filed 06/27/2007 have been fully considered but the are not persuasive.

2. The objection of the drawings filed 6/16/2006 has been withdrawn.

3. Applicant argues that difference between Grunkin patent are not merely the use of an exponential function, as suggested by the Official Action. Another important difference is the use of the bone mineral density in a correlation with a structural parameter obtained from the same two-dimensional image from which the bone mineral density was determined, to determine the mechanical resistance of a bone and that in Grunkin patent the bone mineral density is identified as one of the optional features and even if DMO were utilized in the Grunkin method, Grunkin plainly did not contemplate determining the mechanical resistance of a bone by correlating the bone mineral density as obtained from a given two dimensional image with a structural parameter obtained from the same two dimensional image.

In response, It is true that Grunkin et al does not teach the correlation of BMD with mechanical properties therefore, Examiner used a secondary reference Majundar et al teaches the use of logarithmic transform being applied to determine the exponent, a linear model was used to describe the relationship between QCT- determined BMD and modulus and strength. Moreover, Majundar et al teaches significant differences in the BMD, trabecular architectural measures, elastic modulus, and strength at the different skeletal sites. The primary orientation

axes for most of the specimens was the anatomic superior-inferior (axial) direction. Using the fabric tensor formulation, in addition to BMD, improved the prediction ofYM (Sl), while including some of the architectural parameters significantly improved the prediction of strength. In comparing MR-derived 3D measures with those obtained from 20 pm optical images (n = 18; 9 vertebrae, 9 femur specimens), good correlations were found for the apparent Tb.Sp and Tb.N, moderate correlation was seen for the apparent BV/TV, and poor correlation was found for the apparent Tb.Th. Using these higher resolution images, the fabric tensor formulation for predicting the elastic modulus also showed improved correlation between the measured and calculated modulus(section 1 and section 2.2) .Moreover, the claim teaches that the correlation of the bone mineral density is determined by any means so the use of linear model is one on the means to calculate the correlation. Moreover, Grunkin test result in column 10 explains the relationship between the wrist bone DMO and the cortical resorption index even it is an example but an example is considered prior art information.. Additionally the applicant's argument that the combination of all the features recited in claims 1-,2-3,12-13 makes the applicant's invention patentable different is not found persuasive and thus Grunkin in view of Majunder still reads on the applicant's claimed invention.All remaining arguments are reliant on the aforementioned and addressed arguments and thus are considered to be wholly addressed herein.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1,2,3 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunkin et al.(US 6,226,393) in view of Majumdar et al.(High resolution Magnetic resonance Imaging: Three dimensional trabecular bone architecture and biomechanical properties, 1998)

Grunkin et al teaches process for determining the mechanical resistance of a bone from a digitized two dimensional image, obtained by imaging, characterized in that there is carried out a correlation between the bone mineral density determined from this two dimensional image by any means suitable to this type of image and a structural parameter obtained from the same two dimensional image (as seen in figure 2, there is a strong correlation to densitometry measurement and in particular to wrist BMD , column 10, lines 1-25, see figure 3 and 4). While Grunkin meets a number of the limitations of the claimed invention, as pointed out more fully above, Grunkin fails to specifically teach the correlation of BMD with mechanical properties using the exponential function. Specifically, Majumdar et al. teaches the use of logarithmic transform being applied to determine the exponent, a linear model was used to describe the relationship between QCT-determined BMD and modulus and strength. Because the use mechanical resistance using exponential correlation provide an ideal platform for assessing trabecular architecture in vivo, at multiple skeletal sites longitudinally, and assist in understanding the etiology of osteoporotic and aging changes, for studying osteoporosis progression and therapeutic efficacy. It would have been obvious to one of ordinary skill in the art to use the mechanical resistance in Grunkin correlation method in order to improve the elastic modulus of the 3D architectural parameters combined with bone mineral density (BMD) thus

improving assessment of biomechanical properties. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 2, Majumdar et al. teaches a process for determining the mechanical resistance of a bone according to claim 1, characterized in that one has recourse to a correlation of the exponential type (see figure 3 and page 451, paragraph 2).

As to claim 3 ,12 and 13, Majumdar et al. teaches the process for determination according to claim 1, characterized in that the correlation associating the bone mineral density (see table 2, BMD) and said structural parameter is used to determine the ultimate stress C.sub.u of the bone. (Note that strength and ultimate strain were determined at the first maximum of the stress-strain curve, page 227, column 2, paragraph 3).

Allowable Subject Matter

6. As previously stated in the office action dated 3/27/2007 that Claims 4-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 4 is rewritten in independent form, thereby claims 4-11 are allowed.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jinge Wu can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jingge Wu/
Supervisory Patent Examiner, Art Unit 2624

Nancy Bitar 10/1/2008